DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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December 15,2014

Panthera Dental, Inc.
c/o Mr. David Yungvirt
Third Party Review Group, LLC
45 Rockefeller Plaza, Suite 2000
New York, NY 10111

Re: K143244
Trade/Device Name: The Panthera Anti-Snoring Device
Regulation Number: 21 CFR 872.5570
Regulation Name: Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea
Regulatory Class: II
Product Code: LRK
Dated: December 5, 2014
Received: December 8, 2014

Dear Mr. Yungvirt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Susan Runner DDS, MA

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
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Office of Device Evaluation
Center for Devices and
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*

K143244

Device Name
The Panthera Anti-Snoring Device

Indications for Use *(Describe)*

The Panthera Anti-Snoring Device is intended to reduce or alleviate snoring and mild to moderate obstructive sleep apnea (OSA) in adults.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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5.- 510 (k) Summary

[As required by 21 CFR 807.92]

Date Prepared: 31 October, 2014

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Device Trade Name: **The Panthera Anti-Snoring Device**
Device Common Name: Mandibular repositioning device
Classification: 21 CFR 872.5570 (Class II)
Product: LRK

Predicate: Narval CC (K113201)

Description: The Panthera Anti-Snoring Device is a removable intraoral device used for treating snoring and mild to moderate obstructive sleep apnea. It consists of two custom fabricated splints that fit separately over the upper and lower teeth and engage by means of adjustable rods.

The device functions as a mandibular repositioner, maintaining the lower jaw in a forward position during sleep. This mechanical protrusion acts to increase the patient's pharyngeal space, improving their ability to exchange air during sleep.

The device is a prescription customized for each patient and has an adjustment mechanism enabling the amount of mandibular advancement to be set by the dentist or physician at the time of fitting the device. The device can be adjusted only by the dentist. The maximum protrusion of the device is 15 mm in 1 mm increments.

Intended Use: The Panthera Anti-Snoring Device is intended to reduce or alleviate snoring and mild to moderate obstructive sleep apnea (OSA) in adults.

Technological: The following table displays the differences and similarities between the new Panthera anti-snoring device and one other previously marketed (predicate) device. Equivalence is based on similarities in intended use, materials of construction, design, and operating principles, as summarized in the table below.

Feature	The Panthera Anti-Snoring Device	Narval CC (K113201)
Regulation description	Intraoral devices for snoring and obstructive sleep apnea (OSA)	Intraoral devices for snoring and obstructive sleep apnea (OSA)
Classification	Class II	Class II
Intended Use	To reduce or alleviate snoring and mild to moderate obstructive sleep apnea (OSA) in adults.	To reduce or alleviate snoring and mild to moderate obstructive sleep apnea (OSA) in adults.
Materials of construction	Made from polymers (polyamide type 12), Supplied by EOS Highly resilient and durable biocompatible polymer material and then manufactured through selective laser sintering to allow the device to be strong yet supple as well as flexible yet highly resilient. The device is metal-free, flexible and lightweight	Made from polymers (polyamide type 12), Supplied by EOS Highly resilient and durable biocompatible polymer material and then manufactured through selective laser sintering to allow the device to be strong yet supple as well as flexible yet highly resilient. The device is metal-free, flexible and lightweight
Design	Use the computer-aided design (CAD) and computer-aided manufacturing (CAM) Use CAD that enables a high degree of customization according to the physician or dentist prescription to accommodate the complex dental anatomy of individual patients. The CAM and selective laser sintering	Use the computer-aided design (CAD) and computer-aided manufacturing (CAM) Use CAD that enables a high degree of customization according to the physician or dentist prescription to accommodate the complex dental anatomy of individual patients. The CAM and selective laser sintering

	guarantees precision, accuracy and consistency for each patient. Two customized splints that fit separately over the upper and lower teeth inside the mouth. The lower splint contains a triangular protrusion, allowing the splints to engage by means of interlocking rods on the sides.	guarantees precision, accuracy and consistency for each patient. Two customized splints that fit separately over the upper and lower teeth inside the mouth. The lower splint contains a triangular protrusion, allowing the splints to engage by means of interlocking rods on the sides.
Principle of operation/ **means of mandibular advancement**	Adjustment of the relative position of the splints guides the mandible forward and maintains advancement thus enlarging the airway. The vertical opening of the jaw is not fixed in a single position.	Adjustment of the relative position of the splints guides the mandible forward and maintains advancement thus enlarging the airway. The vertical opening of the jaw is not fixed in a single position
Fixed/ removable	Removable	Removable
Adjustment	Adjusted via the use of interlocking rods placed on the sides of the splints. The shorter the rod, the further the mandible is advanced Easy to titrate and highly adjustable with connecting rods that allow for 15 mm of protrusive range at 1 mm increments. The dentist can simply select a shorter connecting rod until optimal advancement is achieved. Rods are available between 21 mm to 36 mm in 1 mm increments	Adjusted via the use of interlocking rods placed on the sides of the splints. The shorter the rod, the further the mandible is advanced Easy to titrate and highly adjustable with connecting rods that allow for 15 mm of protrusive range at 1 mm increments. The dentist/patient can simply select a shorter connecting rod until optimal advancement is achieved Rods are available between 21 mm to 36 mm in 1 mm increments
Maximum protrusion of the device	15 mm in 1 mm increments	15 mm in 1 mm increments
Supplied sterile/non sterile	Non sterile	Non sterile

Target population	Adults patients	Adults patients
Single Use/ reusable	Reusable	Reusable
Vertical opening	Up to 4 mm	Up to 4 mm
Prescription/ OTC	Prescription only	Prescription only
Recommended Cleaning and Maintenance	Clean daily in lukewarm water with a soft toothbrush. Rinse, dry and store in case provided. Twice weekly use chlorine-free antibacterial orthodontic cleaning solution.	Clean daily in lukewarm water with a soft brush and a mild soap/baking soda. Rinse, dry, and store in case provided. Twice weekly, use the Sonic Cleaner provided with effervescent antibacterial tablet

RISKS: Panthera dental performed no clinical testing. However, an FMEA risk analysis, and evaluation of the materials of construction and design were performed. The function of mandibular advancement devices requires that the prescribing dentist be cognizant of the potential for soreness, soft tissue soreness, and dentition complications (soreness, motion, loosening) by mandibular advancement. Management of these risks is achieved by advising the patient and dentist in the directions for use that early and repeated examination of the fit of the device, and its performance, must be performed in the dental office by the prescribing dentist. The contraindications, warnings, precautions, storage directions, prescription preparation instructions, fitting and adjustment directions are written to avoid potential problems from arising or persisting with the dentition, tissue, or joints, caused by the OSA devices. No new materials are being used in the device; all material (polyamide type12) is already used in the predicate device (Narval CC). No new risks are introduced with the new device that are not present in the predicate device.

Non-Clinical Testing: The non-clinical testing included assessment of the physical properties of the Panthera Ant-Snoring Device and its ability to achieve its intended use. The Panthera Anti-Snoring Device meets the same specifications as set for the predicate device.

A biocompatibility assessment of the device was performed. The purpose of the biocompatibility assessment was to ensure that biocompatibility had been established for the device. The device is biocompatible, based on the similarity of the materials of construction to the predicate device (Narval CC) marketed by ResMed.

Clinical Testing: Human clinical studies were not deemed necessary to evaluate the safety or effectiveness of the Panthera Anti-Snoring Device. The Panthera Anti-Snoring Device does not: Use designs dissimilar from the predicate device and other previously cleared devices under a 510(k); The Panthera Anti-Snoring Device does not use new technologies different from legally marketed intramandibular repositioning devices for treating snoring and mild to moderate obstructive sleep apnea; and the Panthera Anti-Snoring Device does not deviate from the indications for use identified in the predicate device: Narval CC.

Substantial Equivalence Conclusion: The new device, the Panthera Anti-Snoring device, is considered to be substantially equivalent to the predicate based on the following: it has essentially the same intended use and is indicated for the same user population; it has equivalent technological characteristics to the predicate; it does not raise new questions of safety and effectiveness; it is at least as safe and effective as the predicative device.